

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference XXX	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DE99/03972	International filing date (day/month/year) 08 December 1999 (08.12.99)	Priority date (day/month/year) 10 December 1998 (10.12.98)
International Patent Classification (IPC) or national classification and IPC C12N 15/12		
Applicant DEUTSCHES KREBSFORSCHUNGSZENTRUM STIFTUNG DES ÖFFENTLICHEN RECHTS		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 05 July 2000 (05.07.00)	Date of completion of this report 28 November 2000 (28.11.2000)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE99/03972

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-11, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages 1-11, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the drawings:
 pages 1/9-9/9, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE 99/03972

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

The application meets the requirements of PCT Article 33.

1. This report refers to the following documents (the sequence follows that used in the international search report):

- D1: WO-A-97/22625 (INDIANA UNIVERSITY FOUNDATION; PESCOVITZ ORA H (US); WILLIAMS DAVI) 26 June 1997 (1997-06-26)
- D2: TOYODA A ET AL.: 'Human HXC-26 gene' EMBL DATABASE; ACCESSION NUMBER D83389, 19 February 1997 (1997-02-19), XP002135680
- D3: SEDLACK Z. ET AL.: 'X5L gene; XAP-5-like protein.' EMBL DATABASE, ACCESSION NUMBER Y18503, 30 June 1999 (1999-06-30), XP002135681.

The claimed priority of the present claims is valid. Document D3 was therefore not taken into consideration when forming an opinion on those claims.

Novelty pursuant to PCT Article 33(2)

- 2) The prior art does not describe any protein that corresponds to that as per Figure 1 of the application, or a protein that would be 80% or more homologous with that of the application. Claims 1 and 2 are therefore considered novel.
- 3) Nor does the prior art describe a DNA sequence that would code for such a protein. Claims 3 and 4 are therefore also novel.
- 4) Given their reference to one of the aforementioned claims, the subjects and method of Claims 5-11 can also be considered novel.

Inventive step pursuant to PCT Article 33(3)

- 5) Document D1 can be considered the closest prior art for the preparation of the protein and the corresponding DNA sequence of the present invention. D1 describes the 'Growth Hormone Releasing Hormone' and related peptides, as well as their role and use in influencing spermatogenesis.

However, the protein and peptides of D1 are completely different from the protein of the present application; moreover, the prior art documents contain no indication that would lead a person skilled in the art to isolate the protein or DNA sequence of the application.

An inventive step is therefore acknowledged for Claims 1-11 (PCT Article 33(3)).

Industrial applicability pursuant to PCT Article 33(4)

- 6) The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of Claims 9-11 in their present form. Patentability may depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the medical use of a compound (PCT Rule 67.1(iv)); it does, however, allow claims to the first medical use of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.